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| APPLICATION NO. | F | ILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---------------------------------|------|------------|----------------------|-------------------------|------------------|
| 09/876,144 06/08/2001 | | 06/08/2001 | David Hung | 05284.00092 | 6700 |
| 22907 | 7590 | 04/09/2002 | | | |
| BANNER | | | EXAMINER | | |
| 1001 G STREET N W SUITE 1100 | | | | KIM, JENNIFER M | |
| WASHINGTON, DC 20001 | | | | ART UNIT | PAPER NUMBER |
| | | | | 1617 | |
| | | | | DATE MAILED: 04/09/2002 | 5 |

Please find below and/or attached an Office communication concerning this application or proceeding.

| <u> </u> | | | | | | | |
|--|--|--|--|--|--|--|--|
| , | Application No. | Applicant(s) | | | | | |
| | 09/876,144 | HUNG ET AL. | | | | | |
| Office Action Summary | Examin r | Art Unit | | | | | |
| | Jennifer M Kim | 1617 | | | | | |
| The MAILING DATE of this communication app ars on the cover sheet with the correspondence address Period for Reply | | | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply If NO period for reply is specified above, the maximum statutory period with Failure to reply within the set or extended period for reply will, by statute, - Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). Status | 6(a). In no event, however, may a reply be tir within the statutory minimum of thirty (30) day ill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE | nely filed rs will be considered timely. If the mailing date of this communication. ID (35 U.S.C. § 133). | | | | | |
| 1) Responsive to communication(s) filed on <u>08 January</u> | <u>une 2001</u> . | | | | | | |
| 2a) ☐ This action is FINAL. 2b) ☐ Thi | s action is non-final. | | | | | | |
| 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. | | | | | | | |
| Disposition of Claims | expanto quayro, reco cie. Tri | .,,, | | | | | |
| 4) Claim(s) 1-11 is/are pending in the application. | | | | | | | |
| 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | | | |
| 5) Claim(s) is/are allowed. | | | | | | | |
| 6) Claim(s) is/are rejected. | | | | | | | |
| 7) Claim(s) is/are objected to. | • | | | | | | |
| 8) Claim(s) 1-11 are subject to restriction and/or e | lection requirement. | | | | | | |
| Application Papers | | | | | | | |
| 9) The specification is objected to by the Examiner10) The drawing(s) filed on is/are: a) accep | | miner | | | | | |
| Applicant may not request that any objection to the | | | | | | | |
| 11) The proposed drawing correction filed on | | • • | | | | | |
| If approved, corrected drawings are required in reply to this Office action. | | | | | | | |
| 12) The oath or declaration is objected to by the Examiner. | | | | | | | |
| Priority under 35 U.S.C. §§ 119 and 120 | | | | | | | |
| 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). | | | | | | | |
| a) ☐ All b) ☐ Some * c) ☐ None of: | | | | | | | |
| 1. Certified copies of the priority documents have been received. | | | | | | | |
| 2. Certified copies of the priority documents have been received in Application No | | | | | | | |
| Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | | | |
| 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application). | | | | | | | |
| a) The translation of the foreign language provisional application has been received. 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121. | | | | | | | |
| Attachment(s) | | | | | | | |
| 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) | 5) Notice of Informal | y (PTO-413) Paper No(s) Patent Application (PTO-152) | | | | | |

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DETAILED ACTION

Restrictions

- 1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1 and 6-10, drawn to a composition to contact a breast nipple and to prepare a breast for ductal fluid collection comprising two or more of the active agents set forth in claims 1 and 6-10.
 - II. Claims 2-5, drawn to a method of preparing a breast for ductal fluid collection comprising a composition comprising one or more of the active agents set forth in claims 2-5.
 - III. Claim 11, drawn to a method of preparing a patient for a breast duct fluid collection comprising one or more of techniques set forth in claim 11.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions Group I and Group II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process

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for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process of using that product since two or more of the active agents set forth in Group I can be use as a keratolytic agent.

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- 3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.
- 4. Inventions Group II and Group II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation since Group II is related to method of preparing a breast and Group III is related to a method for preparing a patient.
- 5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of

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their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

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Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Further restriction may be required.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer M Kim whose telephone number is 703-308-2232. The examiner can normally be reached on 8:30AM - 5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie can be reached on 703-308-4612. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

EDWARD J. WEBMAN PRIMARIY EXAMINER GRAUD 1530

Theodore J. Criares
Primary Examiner
Art Unit 1617

jmk
April 5, 2002